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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,483	04/02/2004	Jeffrey E. Habben	0803R	3903

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,483	HABBEN ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *1-17,21,22,38-43 and 55-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20,23-37 and 44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/13/06, 1/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-65 are pending.

2. Applicant's election without traverse of Group V, claims 18-20, 23-37 and 44-54 in the reply filed on 6/19/2006 is acknowledged.

Claims 1-17, 21-22, 38-43 and 55-65 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 18-20, 23-37 and 44-54, including SEQ ID NO:1, 3 and 4 are examined in the present office action.

Specification

4. Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. In the instant application, pages 57 and 100-102 of the specification discloses sequences without the use of sequence identifiers.

The specification is objected to for including a blank instead of an application number on pages 30-32.

Priority

5. The Office acknowledges Applicants' claim for domestic priority to application 09/545,334 filed 4/7/2000. Applicant is requested to amend the first paragraph to include the present status of said application, i.e., the U.S. patent number.

Inventorship

6. In view of the papers filed 6/19/2006, the inventorship in this nonprovisional application has been changed by the deletion of Shane E. Abbitt and Xiaomu Niu.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 18-20, 23-36, 44-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 and 44 are indefinite in the recitation "significant". Applicants have not set forth the metes and bounds of "significant". One skilled in the art would not be apprised of the limits of detrimental effects that are encompassed by Applicants' claim.

Claim 33 and 50 are indefinite in the recitation "highly expressed gene". Applicants have not set forth the metes and bounds of "highly expressed gene". One skilled in the art would not be apprised of the limits that render a gene "highly expressed".

Claim 31 is indefinite in the recitation "low-level". Applicants have not set forth the metes and bounds of "low-level". One skilled in the art would not be apprised of the limits that render a promoter as low-level constitutive.

Claims 25-30, 32, 36, 49 and 53 are indefinite in the recitation "zag2.1" or "eep1" or "eep2" or "zap" or "tb1" or "ckx1-2" or "F3.7" or any of the promoter names listed in claim 49. The sole designation of a DNA sequence by "zag2.1" or "eep1" or "eep2" or "zap" or "tb1" or "ckx1-2" or "F3.7" or any of the promoter names listed in claim 49 is arbitrary and creates ambiguity in the claims. For example, the DNA sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different DNA sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18-20, 23-36 and 44-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transgenic plant comprising a recombinant expression cassette stably integrated into the genome thereof, said cassette capable of effecting an increase in

cytokinin activity, or wherein said cassette comprises a polynucleotide encoding a protein involved in cytokinin biosynthesis, or wherein said cassette comprises a polynucleotide encoding isopentenyl transferase, or wherein said expression cassette comprises a promoter which drives low-level constitutive expression of an operably-linked polynucleotide, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancer elements of a highly expressed gene; or a method of modulating cytokinin activity in a plant comprising stably transforming said plant to result in an increase in cytokinin activity, or wherein said polynucleotide encodes a protein involved in cytokinin biosynthesis, or wherein said protein is isopentenyl transferase, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancer elements of a highly expressed gene.

Applicants disclose expression constructs comprising the *Agrobacterium* isopentenyl transferase (IPT) gene of SEQ ID NO:1 operably linked to the maize GLB1, CIM1, LTP2 promoters (page 86, line 11; page 87, lines 11 and 24; page 31, line 11-14; sentence bridging pages 32-33). Applicants disclose the zag2.1, eep1, eep2, zap, tb1, ckx1-2, and F3.7 promoters (page 31).

The written description rejection is directed in part towards:

1) any expression cassette effecting any increase in cytokinin activity,

2) any expression cassette comprising any polynucleotide encoding any protein involved in cytokinin biosynthesis,

3) any polynucleotide encoding any IPT protein,

4) any promoter driving low-level constitutive expression,

5) any expression cassette comprising a reproductive-tissue preferred promoter and one or more enhancer elements of a highly expressed gene.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding any of the 1-5 claimed embodiments as recited above. Applicants only describe a single IPT gene of SEQ ID NO:1 which is from *Agrobacterium* and Applicants only describe specific promoters GLB1, CIM1, LTP2, zag2.1, eep1, eep2, zap, tb1, ckx1-2, and F3.7 promoters. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the any expression cassette that increases cytokinin biosynthesis, or for any expression

cassette that comprises any polynucleotide that encodes any protein involved in cytokinin biosynthesis, or any IPT protein, or any low-level constitutive promoter, or any reproductive tissue promoter or any enhancer elements of a highly expressed gene, it remains unclear what features identify any of the before recited polynucleotides or proteins. Since the genus of said items has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

9. Claims 18-20, 23-36 and 44-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant and method for increasing cytokinin activity comprising transforming a plant with SEQ ID NO:1 or with a nucleic acid encoding an isopentenyl transferase (IPT) protein, wherein the nucleic acid is isolated from *Agrobacterium*, and wherein the nucleic acid is operably linked to the Zag2.1 promoter of SEQ ID NO:3, or Zap promoter of SEQ ID NO:5 or tb1 promoter of SEQ ID NO:17, and wherein the resultant plant has an increased seed yield, does not reasonably provide enablement for a transgenic plant or method comprising any expression cassette capable of effecting an increase in cytokinin activity, or comprising a polynucleotide encoding any protein involved in cytokinin biosynthesis, or encoding any IPT protein, or using any promoter which drives low-level constitutive expression, or using any reproductive-tissue preferred promoter or using any promoter other than the three listed above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a transgenic plant comprising a recombinant expression cassette stably integrated into the genome thereof, said cassette capable of effecting an increase in cytokinin activity, or wherein said cassette comprises a polynucleotide encoding a protein involved in cytokinin biosynthesis, or wherein said cassette comprises a polynucleotide encoding isopentenyl transferase, or wherein said expression cassette comprises a promoter which drives low-level constitutive expression of an operably-linked polynucleotide, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancers elements of a highly expressed gene; or a method of modulating cytokinin activity in a plant comprising stably transforming said plant to result in an increase in cytokinin activity, or wherein said polynucleotide encodes a protein involved in cytokinin biosynthesis, or wherein said protein is isopentenyl transferase, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancers elements of a highly expressed gene.

Applicants disclose expression constructs comprising the *Agrobacterium* isopentenyl transferase (IPT) gene of SEQ ID NO:1 operably linked to the maize GLB1, CIM1, LTP2 promoters (page 86, line 11; page 87, lines 11 and 24; page 31, line 11-14; sentence bridging pages 32-33). Applicants disclose the zag2.1, eep1, eep2, zap, tb1, ckx1-2, and F3.7 promoters (page 31). Applicants disclose a vector comprising the Zag2.1 promoter of SEQ ID NO:3, or Zap promoter of SEQ ID NO:5 or tb1 promoter of SEQ ID NO:17 operably linked to an isolated polynucleotide of SEQ ID NO:1 encoding ipt, and maize and soybean transformation therewith (pages 103-106, Examples 5 and 6). Applicants disclose yield of plants with said constructs was increased compared to wild-type (pages 109-114, Examples 11-12).

Due to the unpredictable nature of plant transformation with proteins that alter hormone activities, one of skill in the art cannot reasonably generate transformed plants with a desired phenotype using a specific isolated gene. Estruch et al (1993, The Plant Journal, 4(2):379-384) teach creating somatic mosaic tobacco plants with the cytokinin-synthesizing (*ipt*) gene in which cells expressing the *ipt* gene are surrounded by cells not expressing the gene. In such plants, ectopic meristems formed on the upper surface of leaves and the ectopic meristems produced both normal and abnormal flower buds. The abnormal buds being characterized by mosaic floral organs and fusion between organs from different whorls. "The occurrence of such abnormalities correlates with an increase in cytokinin content within the floral tissue" (page 379, bottom left column and top right column).

Roeckel et al (1997, Transgenic Research 6(2):133-141) teach transformed canola and tobacco with an IPT gene under the control of the developmentally-regulated, seed-specific 2S albumin promoter from *Agrobacterium*. While IPT mRNA was found only in seeds, effects of

the construct were not limited to seeds: tobacco had reduced roots; canola plants were "surprisingly" taller and had more braches and more seed-bearing structures (page 139). However, yield was not affected, nor was leaf type, leaf number, days to first flower, or days to bolting, in either species. Sa et al (2002, Transgenic Research 11(3):269-278) report that transformed tobacco with IPT from Agrobacterium under the control of a promoter which specifically expresses in anthers, resulted in perturbation in the development of anthers and pollen (page 12, 5th paragraph).

Applicants are claiming any cytokinin biosynthetic enzyme but the biochemical pathway(s) which result in active cytokinins, are still being elucidated. The state-of-the-art teaches there are multiple cytokinin biosynthetic pathways in plants and the investigations are still on going. Takei et al (2001, Journal of Biological Chemistry 276(28):26405-26410) teach multiple routes have been proposed in cytokinin biosynthesis. One such route involves tRNA modification, but because of the high turnover rate of tRNA, it is estimated that the degradation pathway is not a major source of cytokinin (page 26405, paragraph bridging the left and right columns). In addition, Takei et al teach that not all IPT genes cloned from *Arabidopsis* produced active cytokinins (iPMP). For example, *E. coli* transformed with AtIPT2 did not secrete active cytokinin into the culture medium. Taken together, these results imply that not all cytokinin biosynthetic enzymes are known, and because of the various pathways, certain enzymes will have specific substrate specificities that cannot be predicted from the available knowledge at present.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the

respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of any sequence capable of effecting an increase in cytokinin activity as probes or by designing primers to any sequence capable of effecting an increase in cytokinin activity and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when introduced into a plant effect an increase in cytokinin activity.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 18-20, 23-24, 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Amasino et al (November, 1997, U.S. Patent Number 5,689,042).

The claims are drawn to a method of modulating cytokinin activity in a plant or a transgenic plant comprising a recombinant expression cassette capable of effecting an increase in cytokinin activity, wherein said transgenic plant displays enhanced vigor without significant detrimental effects of increased cytokinin activity, seeds of said plant, or wherein said

recombinant expression cassette comprises a polynucleotide encoding a protein involved in cytokinin biosynthesis, or wherein said protein is isopentenyl transferase.

Applicants define vigor of a plant as including, but not limited to, concentration of chlorophyll, and total biomass (page 28, lines 3-12).

Amasino et al teach a genetic construct comprising a DNA sequence encoding an isopentenyl transferase and a transgenic plant transformed with said construct, and seeds of said plant (columns 19-20, claims 1, 8-9, 14-24). Amasino et al teach that plants transformed with the SAG12::IPT construct were phenotypically normal except that the transgenic plant retained high levels of chlorophyll through out flower and seed development, while transgenic plants without said construct exhibited extensive senescence of lower leaves (column 11, lines 24-39). Given Applicants' definition of vigor as discussed above, Amasino et al anticipate the claimed invention.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 18-20, 23-24, 31, 33, 44-48, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Martineau (1995, U.S. Patent Number 6,329,570 B1).

The claims are a method of modulating cytokinin activity in a plant or a transgenic plant comprising transforming said plant to result in an increase in cytokinin activity, or wherein said plant is transformed with a recombinant expression cassette capable of effecting an increase in cytokinin activity, or wherein said expression cassette comprises a female reproductive-tissue-

preferred promoter operably linked to a polynucleotide encoding a protein involved in cytokinin biosynthesis and one or more promoters or enhancer elements of a highly-expressed gene.

Martineau discloses a transgenic plant and method for increasing the rate of boll production and number of bolls produced by a transgenic cotton plant comprising a DNA construct comprising a transcriptional and translational initiation region functional in a cotton ovule integument cell operably linked to a DNA sequence encoding an enzyme or polypeptide that increases the biosynthesis of a growth hormone wherein said enzyme is isopentenyl transferase (column 33-36, claims 1-20). The Office contends that a promoter that expresses in a cotton ovule integument cell is a female reproductive-tissue preferred promoter because the integuments are the outer cell layers of the ovule. Because of the 112 second paragraph indefiniteness of "one or more promoter or enhancer elements of a highly expressed gene" as discussed above, the office does not give said recitation any patentable and weight, and as such, Martineau anticipates the claimed invention.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-20, 23-37 and 44-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,992,237 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious over the claims of Patent No. 6,992,237 B1.

The claims of the instant application are drawn to a transgenic plant comprising a recombinant expression cassette stably integrated into the genome thereof, said cassette capable of effecting an increase in cytokinin activity, or wherein said cassette comprises a polynucleotide encoding a protein involved in cytokinin biosynthesis, or wherein said cassette comprises a polynucleotide encoding isopentenyl transferase, or wherein said expression cassette comprises any of the promoters listed in claims 25-30, or 32 or wherein said expression cassette comprises a promoter which drives low-level constitutive expression of an operably-linked polynucleotide, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancers elements of a highly expressed gene, or wherein the expression cassette comprises the sequences recited in claim 37; or a method of modulating cytokinin activity in a plant comprising stably transforming said plant to result in an increase in cytokinin

activity, or wherein said polynucleotide encodes a protein involved in cytokinin biosynthesis, or wherein said protein is isopentenyl transferase, or wherein said expression cassette comprises a reproductive-tissue preferred promoter and one or more promoters of enhancers elements of a highly expressed gene or wherein said cassette comprises any of the promoters listed in claim 49, or comprises the sequences listed in claim 54.

The claims of U.S. Patent 6,992,237 B1 are drawn to a method of producing a transgenic plant, a method for increasing seed number and/or seed size, a method for producing transgenic plants having increased cytokinin content, a method for producing transgenic plants wherein developing seeds have an increased cytokinin content, or a transgenic plant comprising a construct comprising a seed preferred or seed specific promoter operably linked to an isolated polynucleotide encoding an isopentenyl transferase.

Applicants disclosure that a vector comprising the Zag2.1 promoter of SEQ ID NO:3, or Zap promoter of SEQ ID NO:5 or tb1 promoter of SEQ ID NO:17 operably linked to an isolated polynucleotide of SEQ ID NO:1 encoding ipt, and maize and soybean transformation therewith (pages 103-106, Examples 5 and 6), produced plants with increased seed yield (pages 109-114, Examples 11-12). The Office contends that there is no patentable distinction of using a seed preferred promoter as recited in 6,992,237 B1 as compared to the promoters of the instant application because, for example, the Zap promoter is expressed during flowering (see WO 03/078590, cited on page 31, line 17 of specification) and still generated plants with more seeds. Therefore, it would be obvious to substitute a seed preferred promoter with any of the promoters listed by Applicant in the instant application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

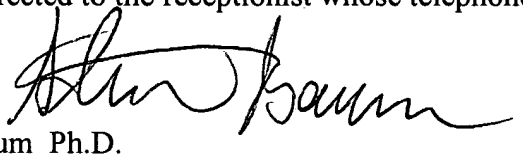
Claim 19 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent would overcome the rejection.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
August 4, 2006